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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/469,399 12/22/99 EDGREN

D ARC2885R1

EXAMINER

HM12/0227

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CHOICE

ART UNIT

PAPER NUMBER

1616

DATE MAILED:

02/27/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/469,399

Applicant(s)

EDGREN ET AL.

Examiner

Frank I Choi

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2. 20) ☐ Other: _____

DETAILED ACTION

Specification

The disclosure is objected to because of the following informalities:

Pg. 25, line 23, "anticholenergetic" should be "anticholinergic" .

Appropriate correction is required.

Claim 6, 11, 19 is objected to because of the following informalities:

Claim 6, line 2, "antihperglycemic" should be "antihyperglycemic".

Claim 11, line 2, "antihperglycemic" should be "antihyperglycemic".

Claim 19, line 2, "anticholonergic" should be "anticholinergic".

Appropriate correction is required.

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

Claims 1-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-25 contain the phrase "adapted to swell in the stomach to facilitate retention of the dosage form in the stomach over a prolonged period of time" which renders the claims indefinite. The phrase appears to define the particular problem that the invention is attempting to solve but it is uncertain how the first layer is to be adapted other than containing the swellable,

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water-soluble polymer. If the swelling of the water-soluble polymer is what solves the problem than the claim should specifically indicate the same.

Claim 4, line 7, the "and" appears to be misplaced, as such, it is uncertain whether the sugars and sodium chloride are part of the first markush group.

Claim 4, lines 5, 11, contain the trademark "Amberlite" which renders the claim indefinite as trademarks identify the source, i.e. manufacturer, and not the product which the formulation of is subject to change by the manufacturer.

Claim 7, lines 3, 4, the phrase "weight percent of the hydroattractant of the second layer is 0 to 60 weight percent" is recited which renders the claim indefinite as Claim 7 must contain more than 0 weight % the hydroattractant in the second layer as it is dependent on claim 4 which contains a hydroattractant in the second layer. Examiner suggests that Applicant use "not more than 60 weight percent" or "up to 60 weight percent, inclusive".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al. (U.S. Pat. 5,534,263) in view of Breitenbach et al.

Wong et al. teach a banded dosage form suitable for oral administration containing polymers which swell upon contact with physiological fluids and active ingredients (See entire reference).

Breitenbach et al. teach a method of preparing multilayer medicaments containing a polymers which swell in physiological fluids (See Columns 2-7) It is taught that the advantage of having multiple layers is that incompatible substances can be separated or the release characteristics of an active ingredient can be controlled (See Column 2, lines 59-68, Column 3, lines 1-5).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose a banded dosage form having at least two layers. However, the prior art amply suggests the same as banded dosage forms and multilayer dosage forms are well known in the art. As such it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation of formulating a dosage form where incompatible substances can be separated or the release characteristic of the active ingredient can be controlled.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-25 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,120,803 in view of Breitenbach et al.

U.S. Patent No. 6,120,803 claim a banded dosage form suitable for oral administration containing polymers which swell upon contact with physiological fluids and active ingredients (See claims 1-12.

Breitenbach et al. is cited here for the same reasons as above and the same is incorporated herein to avoid repetition.

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose a banded dosage form having at least two layers. However, the prior art amply suggests the same as banded dosage forms and multilayer dosage forms are well known in the art. As such it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation of formulating a dosage form where incompatible substances can be separated or the release characteristic of the active ingredient can be controlled.

Therefore, the claimed invention, as a whole, would have been obvious variation of the claims of U.S. Pat. 6, 120,802 to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

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Conclusion

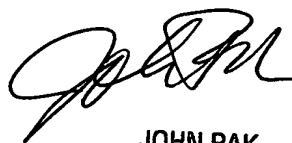
A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machines are (703) 308-4556 or (703) 305-3592.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (703) 308-0067.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. José Dees, can be reached on (703) 308-4628.

FIC

February 26, 2001



JOHN PAK
PRIMARY EXAMINER
GROUP 1600

